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Women's and Children's Health Issues

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

REFERENCE: Docket No. 00D-1350

Dear Sirs:

I was very pleased to have the opportunity to review the Draft Guidance on Combined Oral Contraceptives. It was particularly gratifying to see that much of the original text, in the version of the Guidance that was drafted by Dr. Linda Potter and myself at Family Health International, has been retained. Most of the omissions are less important than the material that is currently included, and these omissions permit the labeling to be shorter, which is itself a good thing.

I have only a few specific comments, as follows:

There is nothing said about COC use for "emergency contraception" purposes, except buried in the footnotes of the pregnancy rate table, which most people are unlikely to read. And yet, the press release regarding this draft Guidance states that one of the items included in the Guidance is "A statement about the potential benefits of using contraceptive pills within 72 hours of unprotected sex to prevent pregnancy." This statement should appear somewhere more prominently than the table footnote.

Under "Warnings," in Section 1.a there is a heading "For products containing desogestrel," which applies only to the next paragraph. However, the placement of this heading makes it appear that it applies to the rest of that section. Perhaps that heading could instead be placed at the beginning of the paragraph, or, alternatively, that paragraph could be moved to the end of the section.

Also in Section 1 under "Warnings" there is a heading missing. The heading "Cerebrovascular disease" should have only one paragraph. Then there should be a new heading "c. Ischemic

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Heart Disease” preceding the paragraph on myocardial infarction. The “Valvular Heart Disease” heading would then be preceded by the letter “d.”

Section 2 under “Warnings,” entitled “Elevated blood pressure,” refers only to women with very high blood pressure. The FHI draft also had an important section, based on the WHO medical eligibility criteria, which I think should be put back in, as follows:

“For women with mild elevation in blood pressure (140-159/90-99) at COC initiation, whose blood pressure is monitored periodically, the advantages of using the method generally outweigh the risks. However, if blood pressure cannot be monitored, then use of COCs is not usually recommended for women with these blood pressure levels unless other more appropriate methods are not available or not acceptable.”

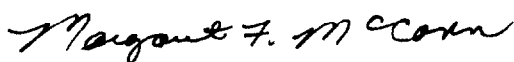
Under the “Precautions” section, number 7 about nursing mothers, the words “at least” should be added before “6 weeks postpartum.” Additional detail about when to start for nursing mothers should be included in the Patient Labeling.

Under “Noncontraceptive Health Benefits,” the last item listed for each of the bulleted sections in the FHI draft has been eliminated. I assume that there were reasons for each of those omissions, but given the pattern I want to mention this to be sure that this wasn’t some kind of typographical error. Originally, “decreased prevalence of premenstrual symptoms” followed the statement about dysmenorrhea; “decreased symptoms of endometriosis” followed the statement about ectopic pregnancy; and “decreased occurrence of symptomatic pelvic inflammatory disease” followed the statement about benign breast tumors.

I will not comment on the version of the Patient Labeling included in this draft, as I have instead commented on the newer version that Dr. Potter has developed – except to say that the very last line of this Patient Labeling says, “For references, see the professional product labeling.” But there are no references listed there! I think that there should, indeed, be references listed, so that the clinician can do further reading on whatever topic is of interest.

I look forward to seeing this revised Guidance in use in the near future.

Sincerely,

A handwritten signature in black ink, reading "Margaret F. McCann". The signature is written in a cursive, flowing style.

Margaret F. McCann, Ph.D.

CC: Lana L. Pauls

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